

REMARKS

Claims 1, 3, 5, 6, 8, 12, 13, 15-18, 20-23, 31, 32, 34-37 and 50 are pending in the present application. Claims 1, 18, 31, 34 and 50 are amended herein to no longer recite “or at least about one hundred CD8⁺ cells”. No new matter is added by these amendments. Upon entry of this response, claims 1, 3, 5, 6, 8, 12, 13, 15-18, 20-23, 31, 32, 34-37 and 50 will be pending in the application.

The Obviousness-Type Double Patenting Rejection

The Examiner has provisionally rejected claims 1, 3, 5, 6 and 18 on the ground of Nonstatutory obviousness-type double patenting as unpatentable over claims 1, 2, 10, 13 and 14 of copending Application No. 10/366,671 (“the ’671 application”) in view of the abstract of Erices *et al.*, *Br. J. Haematol.* 109(1):235-242 (2000). Office Action at page 2. The Applicant will file a terminal disclaimer over the ’671 application when the claims are otherwise in condition for allowance.

The Rejection Under 35 U.S.C. § 112, First Paragraph Should Be Withdrawn

The Examiner has rejected claims 1, 3, 5, 6, 8, 12, 13, 15-18, 20-23, 31, 32, 34-37 and 50 under 35 U.S.C. § 112, first paragraph, as lacking sufficient written description. Applicant respectfully traverses as follows.

The Examiner contends that the disclosure does not sufficiently describe a cytotherapeutic unit comprising a plurality of cells that are CD34⁺ and cells that are CD34⁻ and OCT-4⁺. The present application provides a description of both types of cells, and of a cytotherapeutic unit that comprises such cells.

The written description requirement is satisfied where the application “clearly convey[s] the information that an applicant has invented the subject matter which is claimed” and “put[s] the public in possession of what the applicant claims as the invention.” Manual of Patent Examining Procedure (MPEP), Eighth Edition Incorporating Revision No. 5, § 2163, at page 2100-165 (citing *In re Barker*, C559 F.2d 588, 592 n.4 (C.C.P.A. 1977) and *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998)).

The present application as filed describes cytotherapeutic units comprising cells that are CD34⁻ and OCT-4⁺. The specification also teaches that a cytotherapeutic unit can comprise more than one type of potent cell. *See, e.g.*, paragraphs [0040] and [0043], and Example 2.

Regarding the cells that may be present in the cytotherapeutic units, paragraph [0040] of the application as published discloses cytotherapeutic units that comprise CD34⁺ cells, and cytotherapeutic units that comprise OCT-4⁺ cells. *See* also paragraph [0011]. Paragraphs [0012] and [0022] of the published application further describe cells, in certain cytotherapeutic units, that “may be characterized by the presence of one or more of the following cell surface markers: CD10⁺, CD29⁺, **CD34⁻**, CD38⁻, CD44⁺, CD45⁻, CD54⁺, CD90⁺, SH2⁺, SH3⁺, SH4⁺, SSEA3⁻, SSEA4⁻, **OCT-4⁺**, and ABC-p⁺.” (Emphasis added.) The present application further describes cytotherapeutic units comprising CD34⁺ cells at least at paragraphs [0011] and [0040] and in Examples 1-3. In particular, Example 2 describes a cytotherapeutic unit that comprises CD34⁺ cells and “pluripotential placental cells such as those described in WO 02/064755,” which teaches stem cells that are, *inter alia*, CD34⁻ and OCT-4⁺. *See* paragraph [0061]; *see also* paragraph [0043]. The specification therefore describes cytotherapeutic units comprising both CD34⁺ cells, and CD34⁻ cells and OCT-4⁺ cells, at least some of each of which must be CD34⁻, OCT-4⁺ cells, wherein the cells are obtainable by perfusion. A person of skill in the art would, therefore, appreciate that Applicant had described, and possessed, cytotherapeutic units comprising CD34⁺ cells and cells that are CD34⁻, OCT-4⁺.

Thus, the specification of the present application describes the cell types contained in the claimed cytotherapeutic units, and thus describes the claimed cytotherapeutic units, in satisfaction of 35 U.S.C. § 112, first paragraph. Applicant respectfully requests that this rejection of the claims be withdrawn.

CONCLUSION

Applicant respectfully requests that the present remarks be made of record in the file history of the present application. An early allowance of the application is earnestly requested. The Examiner is invited to contact the undersigned with any questions concerning the application.

Respectfully submitted,

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By: Lawrence S. Graham Reg. No. 49,020
For: Anthony M. Insogna Reg. No. 35,203

JONES DAY
222 East 41st Street
New York, NY 10017-6702
(212) 326-3939